

AMENDED IN ASSEMBLY JANUARY 4, 2016

AMENDED IN ASSEMBLY APRIL 16, 2015

AMENDED IN ASSEMBLY MARCH 26, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 1386

Introduced by Assembly Member Low

February 27, 2015

An act to add Section 4119.4 to the Business and Professions Code, to amend Section 1714.23 of the Civil Code, and to amend Section 1797.197a of the Health and Safety Code, relating to emergency medical care.

LEGISLATIVE COUNSEL'S DIGEST

AB 1386, as amended, Low. Emergency medical care: epinephrine auto-injectors.

(1) Existing law authorizes a prehospital emergency medical care person, first responder, or lay rescuer to use an epinephrine auto-injector to render emergency care to another person, as specified. Existing law ~~also requires the California Emergency Medical Services (EMS) Authority to establish or approve authorized training providers and the minimum standards for training and the use and administration of epinephrine auto-injectors, in consultation with the local emergency medical system agency, the county health department, the manufacturer, the State Department of Health Care Services, and other private organizations. The~~ *auto-injectors. The existing Pharmacy Law* ~~Law~~, also authorizes a pharmacy to dispense epinephrine auto-injectors to a prehospital emergency medical care person, first responder, or lay

rescuer for the purpose of rendering emergency care in accordance with these provisions. A violation of the Pharmacy Law is a crime.

This bill would ~~authorize~~ *permit* an “authorized entity,” as defined, to use an epinephrine auto-injector to render emergency care to another person in accordance with these provisions. The bill would also authorize a pharmacy to furnish epinephrine auto-injectors to an authorized entity pursuant to those provisions. Because a violation of these provisions would be a crime, the bill would impose a state-mandated local program. The bill would ~~also~~ require an authorized entity to *create and maintain a specified operations plan relating to its use of epinephrine auto-injectors, and would require those entities to* submit a report to the State Department of Public Health on incidents related to the administration of epinephrine ~~auto-injectors, and for auto-injectors. The bill would also require~~ the department to issue an annual report summarizing and analyzing the reports submitted to ~~it. the department pursuant to the bill’s provisions.~~

(2) Under existing law, everyone is generally responsible, not only for the result of his or her willful acts, but also for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person, except so far as the latter has, willfully or by want of ordinary care, brought the injury upon himself or herself. Existing law also provides that a prehospital emergency care person, first responder, or lay rescuer who administers an epinephrine auto-injector to another person who appears to be experiencing anaphylaxis at the scene of an emergency situation, in good faith and not for compensation, is not liable for any civil damages resulting from his or her acts or omissions in administering the epinephrine auto-injector, if that person has complied with specified certification and training requirements and standards.

This bill would provide that employees, agents, or other trained individuals of an authorized entity who administers an epinephrine auto-injector to another person who appears to be experiencing anaphylaxis at the scene of an emergency situation, in good faith and not for compensation, is not liable for any civil damages resulting from his or her acts or omissions in administering the epinephrine auto-injector, if that person has complied with specified certification and training requirements and standards. The bill would also provide that an authorized entity located in this state shall not be liable, in this state, for any injuries or related damages that result from the provision or administration of an epinephrine auto-injector by its employees or

agents outside of this state if the entity or its employee or agent would not have been liable for those injuries or related damages had the provision or administration occurred within this state.

The

(3) *The* California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 4119.4 is added to the Business and
2 Professions Code, to read:

3 4119.4. (a) Notwithstanding any other law, a pharmacy may
4 furnish epinephrine auto-injectors to an authorized entity, as
5 defined by Section 1797.197a of the Health and Safety Code, if
6 both of the following requirements are met:

7 (1) The epinephrine auto-injectors are furnished exclusively for
8 use at or in connection with an authorized entity.

9 (2) An authorized health care provider provides a prescription
10 that specifies the quantity of epinephrine auto-injectors to be
11 furnished.

12 (b) *The pharmacy shall label each epinephrine auto-injector*
13 *dispensed with all of the following:*

14 (1) *The name of the person or entity to whom the prescription*
15 *was issued.*

16 (2) *The designations "Section 1797.197a Responder" and "First*
17 *Aid Purposes Only."*

18 (3) *The dosage, use, and expiration date.*

19 (c) *Each dispensed prescription shall include the manufacturer's*
20 *product information sheet for the epinephrine auto-injector.*

21 ~~(b)~~

22 (d) Records regarding the acquisition and disposition of
23 epinephrine auto-injectors furnished pursuant to subdivision (a)
24 shall be maintained by the authorized entity for a period of three
25 years from the date the records were created. The authorized entity
26 shall be responsible for monitoring the supply of epinephrine

1 auto-injectors and ensuring the destruction of expired epinephrine
2 auto-injectors.

3 *(e) The epinephrine auto-injector dispensed pursuant to this*
4 *section may be used only for the purpose, and under the*
5 *circumstances, described in Section 1797.197a of the Health and*
6 *Safety Code.*

7 SEC. 2. Section 1714.23 of the Civil Code is amended to read:
8 1714.23. (a) For purposes of this section, the following
9 definitions shall apply:

10 (1) "Anaphylaxis" means a potentially life-threatening
11 hypersensitivity or allergic reaction to a substance.

12 (A) Symptoms of anaphylaxis may include shortness of breath,
13 wheezing, difficulty breathing, difficulty talking or swallowing,
14 hives, itching, swelling, shock, or asthma.

15 (B) Causes of anaphylaxis may include, but are not limited to,
16 insect stings or bites, foods, drugs, and other allergens, as well as
17 idiopathic or exercise-induced anaphylaxis.

18 (2) "Epinephrine auto-injector" means a disposable drug delivery
19 system with a spring-activated concealed needle that is designed
20 for emergency administration of epinephrine to provide rapid,
21 convenient first aid for persons suffering from anaphylaxis.

22 (b) (1) Any person described in subdivision (b) of Section
23 1797.197a of the Health and Safety Code or employees, agents,
24 or other trained individuals of an authorized entity, as defined by
25 paragraph (2) of subdivision (a) of Section 1797.197a of the Health
26 and Safety Code, who administers an epinephrine auto-injector,
27 in good faith and not for compensation, to another person who
28 appears to be experiencing anaphylaxis at the scene of an
29 emergency situation is not liable for any civil damages resulting
30 from his or her acts or omissions in administering the epinephrine
31 auto-injector, if that person has complied with the requirements
32 and standards of Section 1797.197a of the Health and Safety Code.

33 (2) An authorized health care provider that prescribes *or*
34 *dispenses* an epinephrine auto-injector *or a pharmacist that*
35 *dispenses an epinephrine auto-injector* to a person described in
36 subdivision (b) of Section 1797.197a of the Health and Safety
37 Code or an authorized entity is not liable for any civil damages
38 resulting from any act or omission related to the provision of an
39 epinephrine auto-injector.

1 (3) A person that conducts the training described in subdivision
2 (c) of Section 1797.197a of the Health and Safety Code is not
3 liable for any civil damages resulting from any act or omission
4 related to the acquisition, possession, administration, or provision
5 of an epinephrine auto-injector.

6 (4) An authorized entity located in this state shall not be liable,
7 in this state, for any injuries or related damages that result from
8 the provision or administration of an epinephrine auto-injector by
9 its employees or agents outside of this state if the entity or its
10 employee or agent would not have been liable for those injuries
11 or related damages had the provision or administration occurred
12 within this state.

13 *(5) An authorized entity that possesses and makes available*
14 *epinephrine auto-injectors, including third parties that facilitate*
15 *the availability of epinephrine auto-injectors to an authorized*
16 *entity, is not liable for any injuries or related damages that result*
17 *from any act or omission taken pursuant to this section.*

18 ~~(5)~~
19 (6) This subdivision does not eliminate, limit, or reduce any
20 other immunity or defense that may otherwise be available under
21 state law.

22 (c) The protection specified in subdivision (b) shall not apply
23 in a case of personal injury or wrongful death that results from the
24 gross negligence or willful or wanton misconduct of the person
25 who renders emergency care treatment by the use of an epinephrine
26 auto-injector.

27 (d) Nothing in this section relieves a manufacturer, designer,
28 developer, distributor, or supplier of an epinephrine auto-injector
29 of liability under any other applicable law.

30 SEC. 3. Section 1797.197a of the Health and Safety Code is
31 amended to read:

32 1797.197a. (a) For purposes of this section, the following
33 definitions shall apply:

34 (1) "Anaphylaxis" means a potentially life-threatening
35 hypersensitivity or allergic reaction to a substance.

36 (A) Symptoms of anaphylaxis may include shortness of breath,
37 wheezing, difficulty breathing, difficulty talking or swallowing,
38 hives, itching, swelling, shock, or asthma.

1 (B) Causes of anaphylaxis may include, but are not limited to,
2 insect stings or bites, foods, drugs, and other allergens, as well as
3 idiopathic or exercise-induced anaphylaxis.

4 (2) “Authorized entity” means any entity or organization in
5 connection with, or at which, allergens capable of causing
6 anaphylaxis may be present, including, but not limited to, recreation
7 camps, colleges and universities, day care facilities, youth-sport
8 sports leagues, amusement parks, restaurants, places of
9 employment, and sports arenas.

10 (3) “Epinephrine auto-injector” means a disposable drug delivery
11 system with a spring-activated concealed needle that is designed
12 for emergency administration of epinephrine to provide rapid,
13 convenient first aid for persons suffering from anaphylaxis.

14 (4) “Lay rescuer” means any person who has met the training
15 standards and other requirements of this section but who is not
16 otherwise licensed or certified to use an epinephrine auto-injector
17 on another person.

18 (5) “Prehospital emergency medical care person” has the same
19 meaning as defined in paragraph (2) of subdivision (a) of Section
20 1797.189.

21 (b) A prehospital emergency medical care person, lay rescuer,
22 or employees, agents, or other trained individuals of an authorized
23 entity may use an epinephrine auto-injector to render emergency
24 care to another person if all of the following requirements are met:

25 (1) The epinephrine auto-injector is legally obtained by
26 prescription from an authorized health care provider or from an
27 authorized entity that acquired the epinephrine auto-injector
28 pursuant to subdivision (e). An authorized health care provider
29 may issue a prescription for an epinephrine auto-injector to a person
30 described in this subdivision for the purpose of rendering
31 emergency care to another person, upon presentation of current
32 certification demonstrating that person is trained and qualified to
33 administer an epinephrine auto-injector as a prehospital emergency
34 medical care person or lay rescuer, pursuant to this section or any
35 other statute or regulation.

36 (2) The epinephrine auto-injector is used on another, with the
37 expressed or implied consent of that person, to treat anaphylaxis.

38 (3) The epinephrine auto-injector is stored and maintained as
39 directed by the manufacturer’s instructions for that product.

1 (4) The person using the epinephrine auto-injector has
2 successfully completed a course of training with an authorized
3 training provider, as described in subdivision (c), and has current
4 certification of training issued by the provider.

5 (5) The epinephrine auto-injectors obtained by prehospital
6 emergency medical care personnel pursuant to Section 4119.3 of
7 the Business and Professions Code shall be used only when
8 functioning outside the course of the person's occupational duties,
9 or as a volunteer, pursuant to this section.

10 (6) The Emergency Medical Services System is activated as
11 soon as practicable when an epinephrine auto-injector is used.

12 (c) (1) The authorized training providers shall be approved,
13 and the minimum standards for training and the use and
14 administration of epinephrine auto-injectors pursuant to this section
15 shall be established and approved, by the ~~California Emergency~~
16 ~~Medical Services (EMS) Authority.~~ *authority.* The authority may
17 designate existing training standards for the use and administration
18 of epinephrine auto-injectors by prehospital emergency medical
19 care personnel to satisfy the requirements of this section.

20 (2) The minimum training and requirements shall include all of
21 the following components:

22 (A) Techniques for recognizing circumstances, signs, and
23 symptoms of anaphylaxis.

24 (B) Standards and procedures for proper storage and emergency
25 use of epinephrine auto-injectors.

26 (C) Emergency followup procedures, including activation of
27 the Emergency Medical Services System, by calling the emergency
28 9-1-1 telephone number or otherwise alerting and summoning
29 more advanced medical personnel and services.

30 (D) Compliance with all regulations governing the training,
31 indications, use, and precautions concerning epinephrine
32 auto-injectors.

33 (E) Written material covering the information required under
34 this provision, including the manufacturer product information
35 sheets on commonly available models of epinephrine auto-injectors.

36 (F) Completion of a training course in cardiopulmonary
37 resuscitation and the use of an automatic external defibrillator
38 (AED) for infants, children, and adults that complies with
39 regulations adopted by the ~~EMS Authority~~ *authority* and the

standards of the American Heart Association or the American Red Cross, and a current certification for that training.

(3) Training certification shall be valid for no more than two years, after which recertification with an authorized training provider is required.

(4) The director~~of the authority~~ may, in accordance with regulations adopted by the authority, deny, suspend, or revoke any approval issued under this subdivision or may place any approved training provider on probation upon a finding by the director of an imminent threat to public health and safety, as evidenced by any of the following:

(A) Fraud.

(B) Incompetence.

(C) The commission of any fraudulent, dishonest, or corrupt act that is substantially related to the qualifications, functions, or duties of training program directors or instructors.

(D) Conviction of any crime that is substantially related to the qualifications, functions, or duties of training program directors or instructors. The record of conviction or a certified copy of the record shall be conclusive evidence of the conviction.

(E) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this section or the regulations promulgated by the authority pertaining to the review and approval of training programs in anaphylaxis and the use and administration of epinephrine auto-injectors, as described in this subdivision.

(d) (1) The authority shall assess a fee pursuant to regulation sufficient to cover the reasonable costs incurred by the authority for the ongoing review and approval of training and certification under subdivision (c).

(2) The fees shall be deposited in the Specialized First Aid Training Program Approval Fund, which is hereby created in the State Treasury. All moneys deposited in the fund shall be made available, upon appropriation, to the authority for purposes described in paragraph (1).

(3) The authority may transfer unused portions of the Specialized First Aid Training Program Approval Fund to the Surplus Money Investment Fund. Funds transferred to the Surplus Money Investment Fund shall be placed in a separate trust account, and shall be available for transfer to the Specialized First Aid Training

1 Program Approval Fund, together with the interest earned, when
2 requested by the authority.

3 (4) The authority shall maintain a reserve balance in the
4 Specialized First Aid Training Program Approval Fund of 5 percent
5 of annual revenues. Any increase in the fees deposited in the
6 Specialized First Aid Training Program Approval Fund shall be
7 effective upon determination by the authority that additional
8 moneys are required to fund expenditures pursuant to subdivision
9 (c).

10 (e) An authorized health care provider may prescribe epinephrine
11 auto-injectors to an authorized entity or to an employee or agent
12 of ~~which~~ *that an authorized entity who* holds a ~~current~~ *valid*
13 certification demonstrating that the person is trained and qualified
14 to administer an epinephrine auto-injector as a lay rescuer.
15 Epinephrine auto-injectors acquired by an authorized entity shall
16 be stored in a location readily accessible in an emergency and in
17 accordance with the epinephrine auto-injectors instructions for use
18 and any additional requirements that may be established by the
19 ~~EMS Authority.~~ *authority.*

20 (f) An authorized entity that possesses and makes available
21 epinephrine auto-injectors shall ~~submit~~ *do both of the following:*

22 (1) *Create and maintain on its premises an operations plan that*
23 *includes all of the following:*

24 (A) *The name and contact number for the authorized health*
25 *care provider who prescribed the epinephrine auto-injector.*

26 (B) *Where and how the epinephrine auto-injector will be stored.*

27 (C) *The names of the designated employees or agents who have*
28 *completed the training program required by this section and who*
29 *are authorized to administer the epinephrine auto-injector.*

30 (D) *How and when the epinephrine auto-injector will be*
31 *inspected for an expiration date.*

32 (E) *The process to replace the expired epinephrine auto-injector,*
33 *including the proper disposal of the expired epinephrine*
34 *auto-injector.*

35 (2) *Submit to the State Department of Public Health, on a form*
36 *developed by the State Department of Public Health, a report of*
37 *each incident on the authorized entity's premises that involves the*
38 *administration of an epinephrine auto-injector. The State*
39 *Department of Public Health shall annually publish a report that*

1 summarizes and analyzes all reports submitted to it under this
2 subdivision.

3 (g) This section shall not apply to a school district or county
4 office of education, or its personnel, that provides and utilizes
5 epinephrine auto-injectors to provide emergency medical aid
6 pursuant to Section 49414 of the Education Code.

7 (h) This section shall not be construed to limit or restrict the
8 ability of prehospital emergency medical care personnel, under
9 any other statute or regulation, to administer epinephrine, including
10 the use of epinephrine auto-injectors, or to require additional
11 training or certification beyond what is already required under the
12 other statute or regulation.

13 SEC. 4. No reimbursement is required by this act pursuant to
14 Section 6 of Article XIII B of the California Constitution because
15 the only costs that may be incurred by a local agency or school
16 district will be incurred because this act creates a new crime or
17 infraction, eliminates a crime or infraction, or changes the penalty
18 for a crime or infraction, within the meaning of Section 17556 of
19 the Government Code, or changes the definition of a crime within
20 the meaning of Section 6 of Article XIII B of the California
21 Constitution.